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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,618	07/17/2007	Mairead Kehoe-Whistance	KEHOE1A	1340

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EXAMINER	
DUFFY, BRADLEY	

ART UNIT	PAPER NUMBER
1643	

MAIL DATE	DELIVERY MODE
09/10/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/575,618	KEHOE-WHISTANCE ET AL.	
	Examiner	Art Unit	
	BRADLEY DUFFY	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2007*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33,38 and 39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-33 and 38 and 39* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1 The preliminary amendment filed July 17, 2007 is acknowledged and has been entered. Claims 9, 10, 15, 17, 29, 21, 22, 27, 31, 38 and 39 have been amended. Claims 34-37 have been canceled.

2. Claims 1-33 and 38-39 are pending in the application and are currently subject to restriction.

Election/Restrictions

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim 4, drawn to a method of treating breast cancer which comprises administering to a subject suffering from breast cancer, a first amount of anti-estrogenic steroid agent, effective to reduce the level or activity of at least one estrogenic steroid in the subject, and a second amount of an immunogen comprising a MUC1 epitope, effective to contribute to the development of a protective immune response to said breast cancer, where said first and second amounts are, at least in combination, therapeutically effective against at least some breast cancers.

Group II, claim 5, drawn to a method of treating breast cancer which comprises administering to a subject suffering from breast cancer, a first

amount of anti-estrogenic steroid agent, effective to reduce the level or activity of at least one estrogenic steroid in the subject, and a second amount of an immunogen comprising a carbohydrate epitope, effective to contribute to the development of a protective immune response to said breast cancer, where said first and second amounts are, at least in combination, therapeutically effective against at least some breast cancers.

Group III, claim 6, drawn to a method of treating breast cancer which comprises administering to a subject suffering from breast cancer, a first amount of anti-estrogenic steroid agent, effective to reduce the level or activity of at least one estrogenic steroid in the subject, and a second amount of an immunogen comprising STn, effective to contribute to the development of a protective immune response to said breast cancer, where said first and second amounts are, at least in combination, therapeutically effective against at least some breast cancers.

Group IV, Claims 32, 33, 38 and 39, drawn to a therapeutic composition or a kit comprising (a) at least one anti-estrogenic steroid agent, and (b) at least one immunogenic agent.

4. Claims 1-3 and 7-31 are linking claims, linking the inventions of Groups I-III. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s). Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination in the instant application. Applicants are advised that if any such claims depending from or including all the limitations of the allowable linking claims are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the

claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

5. The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

To have a general inventive concept under PCT Rule 13.1, the inventions need to be linked by a special technical feature. In this case while the inventions do not appear to linked by a special technical feature, it is noted that the claim 1 recites the technical feature of administering to a subject suffering from breast cancer, a first amount of anti-estrogenic steroid agent and a second amount of an immunological agent. This claim lacks an inventive step over US 6,627,196 (Baughman et al, 9/03). US 6,627,196 teaches administering to a subject suffering from breast cancer, the anti-estrogenic steroid, tamoxifen and a second amount of the immunological agent, trastuzumab (see entire document, e.g., column 33). Since US 6,627,196 teaches the technical feature recited in claim 1, it is not a special technical feature and the groups do not relate to a single general inventive concept as required under PCT Rule 13.1. Furthermore, PCT Rules 13.1 and 13.2 do not provide for a single general inventive concept to comprise more than the first mentioned product, the first mentioned method for making said product, and the first mentioned method for using said product.

For these reasons, the special technical feature of the invention of Group I is administering to a subject suffering from breast cancer, a first amount of anti-estrogenic steroid agent and a second amount of an immunogen comprising a MUC1 epitope.

The special technical feature of the invention of Group II is administering to a subject suffering from breast cancer, a first amount of anti-estrogenic steroid

agent and a second amount of an immunogen comprising a carbohydrate epitope.

The special technical feature of the invention of Group III is administering to a subject suffering from breast cancer, a first amount of anti-estrogenic steroid agent and a second amount of an immunogen comprising STn.

The special technical feature of the invention of Group IV is making a composition or a kit comprising (a) at least one anti-estrogenic steroid agent, and (b) at least one immunogenic agent.

Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

6. This application contains claims directed to more than one species of the generic inventions of Groups I-III. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of the processes of Groups I-III are as follows:

Administering an anti-estrogenic steroid agent selected from the group of: toremifene, tamoxifen, droloxifene, trioxifene, aminoglutethimide, anastrozole, vorozole, letrozole, liarozole, megastrole, exemestane, formestane geoselin acetate, megestrol acetate, clomifene, aroxifene, raloxifene, LY 117018 and SERM EM-652.

7. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by

37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

As set forth above, the prior art of US 6,627,196 (Baughman et al, 9/03) teaches administering to a subject suffering from breast cancer, the anti-estrogenic steroid, tamoxifen and a second amount of the immunological agent, trastuzumab (see entire document, e.g., column 33); accordingly, the claimed methods which administer an anti-estrogenic steroid do not define a contribution over the prior art. Therefore, the subject matter of these processes, as a whole, lacks a special technical feature that links the different species of anti-estrogenic steroid agents of the inventions to form a single general inventive concept under PCT Rule 13.1.

Accordingly, the different species of anti-estrogenic steroid agents do not share the same or corresponding special technical feature so as to form a single general inventive concept under PCT Rules 13.1 and 13.2.

9. **Applicant is advised that the reply to this requirement to be complete must include (i) an election of a single invention to be examined and an election of the species or invention to be examined** even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention and the elected species of invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered

timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

If claims are added after the election, applicant must indicate which of these claims are readable upon the elected invention.

Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed

product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brad Duffy whose telephone number is (571) 272-9935. The examiner can normally be reached at Monday through Friday from 7:00 AM to 4:30 PM, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached at (571) 272-0832. The official fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through

Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Brad Duffy
571-272-9935

/Stephen L. Rawlings/
Primary Examiner, Art Unit 1643

/bd/
Examiner, Art Unit 1643
September 4, 2009